PATENT

Attorney Docket No. 5866.200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas Buch-Rasmussen

Art Unit: 1623

Application No. 09/550,857

Examiner: Young, Josephine

Filed: April 17, 2000

For: DRY MOULDABLE DRUG FORMULATION

DECLARATION UNDER 37 C.F.R. § 1.132
OF THOMAS BUCH-RASMUSSEN

Commissioner for Patents
Washington, D.C. 20231

I, Thomas Buch-Rasmussen, hereby state:

1. I am employed by Novo Nordisk A/S, Denmark in the position of Manager. I have been actively involved in professional chemistry-related research, including research in the Medical device field for over 15 years. I hold a Master Degree from the Technical University of Denmark (DTU) from 1987 in the field of chemistry. I also hold a Nordic Industrial Research degree from 1989 in the field of Biosensors. Upon graduating from DTU, I was employed by Radiometer Medical in the field of Biosensors. Such work involved Analytical chemistry, Electrochemistry and Material Science. From 1990 to present, I am

employed by Novo Nordisk A/S in the capacity of Research scientist, project Manager and Manager. Such work involved Analytical chemistry and Material science within the Medical Device field.

2. I am co-inventor on the above-identified U.S. application.

3. I am familiar with claim 1 submitted with this Declaration and the most recent Office Action in the above-referenced Application.

4. In 1999, I was involved with the development of needle-shaped, solid pharmaceutical composition for parenteral injection (hereinafter designated "needles") and was very familiar with the state of the art in such technology. As part of my professional occupation, I regularly discussed the development of such needles with co-workers and others in the field.

5. Prior to the invention embodied in this application, I did not have any expectation that a pharmaceutical composition having more than about 40% of its weight made up of a therapeutic agent, distributed homogenously through the composition, would be able to penetrate skin. Indeed, the fact that such a composition can penetrate the skin was surprising to me, given the common view that a very high content or an increased number of therapeutic agent in a polymeric composition would render the composition unable to penetrate skin. To my recollection, there was no publications or other materials available at that time that taught or suggested such a pharmaceutical composition could penetrate the skin.

6. I have reviewed the disclosure and examples provided in Roser et al., International Patent Application WO 96/03978 (hereinafter referred to as the Roser '978 PCT application), which is cited in the most recent Office Action. I am aware that the Roser '978 PCT application describes a pharmaceutical composition where "more than 20% weight percent [sic] of organic molecules can be incorporated into the HDC delivery systems" (see page 24, bottom paragraph) and indicates that such organic molecule "guest substances" can be or include "pharmaceutical agents."

7. Even given the disclosure of the Roser '978 PCT application before the filing date, I would still not have expected that a pharmaceutical composition, having at least about 40% of its weight composed of a therapeutic agent homogenously distributed through the composition, would be able to penetrate skin. In this respect, I note that the Roser '978 PCT application offers no data that indicates such a composition could penetrate the skin and, furthermore, provides no guidance or suggestion that would have overcome my doubt that such a composition could in fact penetrate the skin. In this regard, I note that the minimum amount of therapeutic agent called for by claim 1 submitted herewith is at least approximately two times the amount of therapeutic agent contained any composition specifically described in the Roser '978 PCT application. For at least these reasons, I find the discovery that a composition containing at least about 40% therapeutic agent (by weight) can penetrate the skin to be surprising even over the teachings of the Roser '978 PCT application.

8. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 21. NOV. 2003

Thomas Buch-Rasmussen